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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,990	06/26/2001	Solo Goldstein	ADIR359/lw	9535

25666 7590 04/09/2003

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EXAMINER	
ROBINSON, BINTA M	
ART UNIT	PAPER NUMBER
1625	10

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/888,990	GOLDSTEIN ET AL.	
	Examiner	Art Unit	
	Binta M. Robinson	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-29 and 31-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

The examiner has noted that several radicals were not defined in the restriction made at paper no. 6, so the restriction is revised below:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 19-36, drawn to a compound of claim 19 where p and n are as claimed, R1, and R2 are H, linear or branched (C1-C6) alkyl, aryl, and aryl-(c1-C6)alkyl in which alkyl is linear or branched, X is equal to oxygen or sulphur, Y is equal to pyridyl, and pharmaceutical compositions, classified in class 546, subclass 300.

II. Claims 19-36, drawn to a compound of claim 19 where p and n are as claimed, R1, and R2 are H, linear or branched (C1-C6) alkyl, aryl, and aryl-(c1-C6)alkyl in which alkyl is linear or branched, X is equal to –CH=CH-, Y is equal to pyridyl, and pharmaceutical compositions, classified in class 546, subclass 300

III. Claims 19-36, drawn to a compound of claim 19 where p and n are as claimed, R1, and R2 are H, linear or branched (C1-C6) alkyl, aryl, and aryl-(c1-C6)alkyl in which alkyl is linear or branched, X is equal to —HC=N-O-, Y is equal to pyridyl, and pharmaceutical compositions, classified in class 546, subclass 300

IV. Claims 19-36, drawn to a compound of claim 19 where p and n are as claimed, R1, and R2 are H, linear or branched (C1-C6) alkyl, aryl, and aryl-(c1-C6)alkyl in which alkyl is linear or branched, X is equal to –O-

CH2-CH=CH-, Y is equal to pyridyl, and pharmaceutical compositions, classified in class 546, subclass 300.

V. Claims 19-36, drawn to a compound of claim 19 where p and n are as claimed, R1, and R2 are H, linear or branched (C1-C6) alkyl, aryl, and aryl-(c1-C6)alkyl in which alkyl is linear or branched, X is equal to –CH=CH-, Y is –C(O)-A, -C(S)-A, A is pyridyl or quinolinyl, and pharmaceutical compositions, classified in class 546, subclass 166

VI. Claims 19-36, drawn to a compound of claim 19 where p and n are as claimed, R1, and R2 are H, linear or branched (C1-C6) alkyl, aryl, and aryl-(c1-C6)alkyl in which alkyl is linear or branched, X is equal to –CH=CH-, Y is carbocyclic aryl, and pharmaceutical compositions, classified in class 568, subclass 77

VII. Claims 19-36, drawn to a compound of claim 19 where p and n are as claimed, R1, and R2 are H, linear or branched (C1-C6) alkyl, aryl, and aryl-(c1-C6)alkyl in which alkyl is linear or branched, X is equal to –CH=CH-, Y is –C(O)-A, -C(S)-A, A is thienyl or furyl, and pharmaceutical compositions, classified in class 549, subclass 70

VIII. Claims 19-36, drawn to a compound of claim 19 where p and n are as claimed, R1, and R2 are H, linear or branched (C1-C6) alkyl, aryl, and aryl-(c1-C6)alkyl in which alkyl is linear or branched, X is equal to –CH=CH-, Y is –C(O)-A, -C(S)-A, A is oxazolyl, isoxzaolyl, and pharmaceutical compositions, classified in class 548, subclass 215.

IX. Claims 19-36, drawn to a compound of claim 19 where p and n are as claimed, R1, and R2 are H, linear or branched (C1-C6) alkyl, aryl, and aryl-(c1-C6)alkyl in which alkyl is linear or branched, X is equal to –CH=CH-, Y is –C(O)-A, -C(S)-A, A is imidazolyl, and pharmaceutical compositions, classified in class 548 subclass 333.5

X. Claims 19-36, drawn to a compound of claim 19 where p and n are as claimed, R1, and R2 are H, linear or branched (C1-C6) alkyl, aryl, and aryl-(c1-C6)alkyl in which alkyl is linear or branched, X is equal to –CH=CH-, Y is –C(O)-A, -C(S)-A, A is thiazolyl or isothiazolyll, and pharmaceutical compositions, classified in class 548, subclass 200

XI. Claims 19-36, drawn to a compound of claim 19 where p and n are as claimed, R1, and R2 are H, linear or branched (C1-C6) alkyl, aryl, and aryl-(c1-C6)alkyl in which alkyl is linear or branched, X is equal to –CH=CH-, Y is –C(O)-A, -C(S)-A, A is pyrazinyl, and pharmaceutical compositions, classified in class 548, subclass 356.1

XII. Claims 19-36, drawn to a compound of claim 19 where p and n are as claimed, R1, and R2 are H, linear or branched (C1-C6) alkyl, aryl, and aryl-(c1-C6)alkyl in which alkyl is linear or branched, X is equal to –CH=CH-, Y is –C(O)-A, -C(S)-A, A is pyrimidinyl, and pharmaceutical compositions, classified in class 544, subclass 336

The inventions are distinct, each from the other because of the following reasons:

In the instant case the different inventions have achieved a separate status in the art, have separate fields that aren't coextensive, and are capable of supporting separate patents. Further, a prior art reference that would anticipate the claims under 35 USC 102(b) would not render obvious the same claim(s) under 35 U. S. C. 103 (a) with respect to another member. Searching the entire genus would be a burden on the USPTO in terms of time and expense.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

By virtue of the applicant's elected species which falls into Group I, Group I will be examined. If Group II is prosecuted further in a divisional application, then it may be subject to further restriction.

The unelected portions of claims 19-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

(modified rejection)

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19-29 and 31-36 in part are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the radicals, R1

and R2 forming together with the nitrogen carrying them all 5 to 7 membered saturated carboxyclic system, Y equal to all heteroaryl-(C1-C6)alkyl, R3 and R4 forming together with the nitrogen carrying them a monocyclic, or bicyclical (C3-C10 system) and A equal to all heteroaryl rings. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to ***In re Wands***, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte*** Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

Claim(s) 31 in part is rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The disease being treated by treating a condition where specific nicotinic ligands of alpha4beta2 receptors are not specifically stated. The specification must contain one practical utility in currently available form. The inhibition of an enzyme must be related to a disease that needs to be improved and this disease needs to be recited. There is no reasonable assurance that these compounds will have all of the alleged properties or have the applicants supplied the supporting data. The applicant is referred to ***In re Fouche*** 169 USPQ 429 ccpa, 1971, MPEP 716.02 B. The applicant is referred to ***In re Wands***, 858 f.2d 731, 737, 8

USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte Foreman*** 230 USPQ 546 (Bd. Of App. And Inter 1986).

Claim 32 in part is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the method of treating all of the various diseases claimed, many of which are unrelated.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the applicant does not indicate which compounds where tested in pharmacological studies.

In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

(old rejection)

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim(s) 35-36 in part are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 35-36 are indefinite for being improper product use claims. Applicant is referred to Clinical Products v. Brenner -Commissioner of Patents) 149 USPQ 475 (District Court DC 66) Ex parte Dunki 153 USPQ 678 (Bd of Appeals 1967).

Claim 30 in part is objected to because it is based on a rejected claim.

The applicant's declaration has been considered, but is not a showing that is commensurate with the scope of the claims and thus does not overcome the 112, first paragraph rejections. See in re Lindner 173 USPQ 356 (ccpa 1973).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Alan L. Rotman

ALAN L. ROTMAN
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Binta Robinson

March 27, 2003